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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,498	10/27/2004	Hansjorg Reimann	DECLE96.001APC	4048

20995 7590 12/29/2008

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
12/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/509,498	REIMANN ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 22, 2008 has been entered.

Amendment Entry

2. The amendment filed September 22, 2008 has been entered. Claims 1-6 and 8-12 have been amended. Claim 7 has been cancelled. Claims 1-6 and 8-12 are under consideration in this office action.

Withdrawal of Objections and Rejections

3. The following objections and rejection have been withdrawn in view of applicants' amendments and arguments:

a) The objection of claim 1 under 37 CFR 1.75 (c);

b) The scope of enablement rejection of claims 1-11 under 35 U.S.C. 112, first paragraph; and

c) The rejection of claims 5 and 9 under 35 U.S.C. 112, second paragraph.

Response to Arguments

4. Applicant's arguments filed September 22, 2008 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dalemans et al., (WO 99/30733).

The claims are drawn to an immunogenic composition suitable for administration to a vertebrate host, which comprises: (a) a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;(b) a protein antigen immunogenic component comprising at least one protein antigen selected from the group consisting of model protein antigens and immunogenic protein antigens; and (c) a mineral-based, negatively charged adjuvant wherein said mineral-based negatively charged adjuvant is preincubated or subsequently mixed with said at least one protein

antigen immunogenic component prior to formulating with said polynucleotide immunogenic component.

The claims are also drawn to a method of making the combined immunogenic composition , comprising preincubating or subsequently mixing the mineral-based, negatively charged adjuvant with said at least one protein antigen immunogenic component; and adding said polynucleotide immunogenic component to the adjuvant protein mixture to form the combined immunogenic composition.

However, Dalemans et al., teach the instant invention.

Response to Arguments

6. Applicant's arguments filed September 22, 2008 have been fully considered but they are not persuasive.

Applicants assert that the order of mixing the components of the composition results in a structure in toto which differs from the structures of the composition which were made by a different order of mixing the components. However, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP § 2145 generally for case law pertinent to the consideration

of applicant's rebuttal arguments. In case, applicants' generic assertions about [A], [B] and [C] re not persuasive, since the assertions are not specific and do not provide any evidence that the composition of the prior art and the instantly claimed composition have any structural differences. Moreover, the immunogenic composition of Dalemans et al., teach unexpected significant enhancement of both the humoral and cell mediated immune response.

Furthermore, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced *in-situ* does not change the end product.). Therefore applicants' argument is not persuasive.

"The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than

when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). In this case, applicants claim that neither the specific order of mixing was disclosed nor the specific result end result. However, the prior art structure of Dalemans et al., has the same components, (a) a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide immunogenic component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;(b) a protein antigen immunogenic component comprising at least one protein antigen selected from the group consisting of model protein antigens and immunogenic protein antigens; and (c) a mineral-based, negatively charged adjuvant wherein said mineral-based negatively charged adjuvant is preincubated or subsequently mixed with said at least one protein antigen immunogenic component prior to formulating with said polynucleotide immunogenic component, thus the compositions of Dalemans et al, meets the claim limitations. Dalemans et al., teach the DNA + protein complex can be administered by combining the two or admixing to permit one administration wherein the DNA and protein are admixed, just prior to use or when during manufacturing (page 9, lines 8-11).

Dalemans et al., teach formulations previously combining the protein antigen and the adjuvant (page 11, lines 3-8).

It is noted that while Dalemans et al., do disclose simultaneous administration, Dalemans et al., also clearly teach combined or admixed administration. Therefore applicants' arguments are not persuasive. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Therefore applicant's argument is not persuasive especially when considering that Dalemans et al., disclose combined administration of the same instantly claimed immunogenic composition; thus applicants' argument is not persuasive.

Applicant argues that Dalemans et al., teach away from the claimed invention because of the statements that the combination of the DNA + protein can obviate the need for immunostimulants. Dalemans et al., states "the polynucleotides, polypeptides and polynucleotide + polypeptide mixture (complex) of the present invention, when adjuvanted, are preferably adjuvanted in the formulation of the invention" (page 9, lines 18-20). Dalemans et al., then provides a long list of suitable adjuvants. Therefore,

applicants' assertion that Dalemans et al teach away from the use of adjuvants is not persuasive especially when Dalemans et al., teach the use of the exact same adjuvants disclosed by applicant. Furthermore, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims.

Applicants argue that Dalemans et al., do not provide an enabling disclosure because it does not teach any *in vivo* experiments or challenge experiments. However the lack of an in vivo example is irrelevant because Dalemans et al., teach the exact

same immunogenic composition comprises the same instantly recited components, i.e., (a) a polynucleotide immunogenic component comprising at least one polynucleotide encoding at least one antigen;(b) a protein antigen immunogenic component comprising at least one protein antigen selected from the group consisting of model protein antigens and immunogenic protein antigens; and (c) a mineral-based, negatively charged adjuvant wherein said mineral-based negatively charged adjuvant.

Applicants argues that Dalemans et al., do not provide the most effective route of administration; however it is noted that Dalemans et al., at page 12 discloses dosage and routes of administration of the immunogenic complex. Applicants argue that the synergistic effect of Dalemans et al., is not conclusive and do not provide results regarding the cellular responses of various combinations. However, the standard for an enabling disclosure is not that the reference provides the exact same experiments disclosed by applicant. Rather, the issue is that a reference, such as Dalemans et al., may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Furthermore, something which is old does not become patentable upon the assertion or discovery of a new property and the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. Thus the claiming of a new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Therefore, applicants' arguments about the difference of

Dalemans are not persuasive, especially when Dalemans et al., teach the same immunogenic composition and method of making the composition. Therefore applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645